Histopathology Laboratory Handbook

Version 22

Distribution List

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Document review history

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November 2008	A. Armstrong	Reviewed and turnaround times for tests added
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23/06/2023	A. Armstrong	Updated to correct Non-gynaecology TAT's
05/02/2025	A. Armstrong	Updated to reflect revised 2022 UKAS standards

Contents

Introduction

1. Introduction

The Histopathology Laboratory provides a high-quality, cost-effective service to the Wirral University Teaching Hospital NHS foundation trust, GPs and community hospitals within the Wirral Clinical Commissioning Group area and is a referral centre for specialist services for other trusts and Clinical Commissioning Groups outside the Wirral. It is continually upgrading the test repertoire offered to reflect developments in the medical field.

The Laboratory services include.

- Histopathology
- Immunocytochemistry
- Post-mortem Autopsy
- Non-Gynaecological Cytology

The laboratories are staffed by qualified and experienced medical, scientific, technical and support personnel.

1.1 Quality Management

The laboratory is a United Kingdom Accreditation Service (UKAS) accredited medical laboratory No 8836.

The laboratory and Mortuary are subject to external accreditation by the Human Tissue Authority (HTA). The Mortuary is fully licensed, and the licence number is 12027.

The laboratory runs a comprehensive quality management system and participates in all relevant National Quality Assurance Schemes, laboratory and pathologists as well as operating a schedule of internal quality audit, corrective action, and quality improvement.

The laboratory is accredited for training by the Health and Care Professions Council, The Royal College of Pathologists, and the Institute of Biomedical Science.

1.2 Accredited Scope of Practice

As part of ISO15189 accreditation, tests within the department are individually accredited and form the Laboratory's schedule of accreditation. This means that certain tests may not be accredited to ISO15189 as they may fall outside of this

scope of accreditation. The department's schedule of accreditation is published on the UKAS website and for the current list of accredited tests please refers to this website. 8836 Medical Single (ukas.com)

1.3 User Satisfaction

As part of our quality management system, and more importantly to ensure we are meeting the needs of our users, we are always keen to receive any comments regarding the quality of the service the laboratory provides or any suggestions regarding how we can improve the service.

Please feel free to email or contact the departmental manager or laboratory director with any feedback regarding the service.

Cellular Pathology –

Laboratory Manager Alistair Armstrong alistair.armstrong@nhs.net
Laboratory Director Dr Anshu Awasthi anshu.awasthi@nhs.net,

Key Laboratory Information

2. Key Laboratory Information

2.1 Current Location of the Departments

The department is located in a building at the Northwest corner of Arrowe Park Hospital, outside the main hospital building and close to the tall chimney. The department is sign-posted on the main hospital maps. The Mortuary is located on the Basement level in the main hospital and is fully sign-posted from the hospital main entrance.

The postal Address of the department is.

The postal address is: -	**Histopathology Laboratory Wirral University Teaching Hospital NHS Foundation Trust, Arrowe Park Hospital, Wirral, CH49 5PE**	**Tel 0151 678 5111 Ext 2563 Fax 0151 604 1733**

2.2 Laboratory and Mortuary Opening Hours

The Department is open between the hours of 0830 hours and 1730 hours Monday to Friday. There are no formal arrangements for processing samples out of hours although this may be possible in cases of urgent clinical need where the case has been discussed with a Consultant Histopathologist and they have given permission for urgent processing to take place.

The Mortuary operates from 0800 to 1600 Monday to Friday. There is an on-call facility that provides a mortuary service out of these hours. Outside these hours, the duty Mortuary technician can be contacted via the hospital switchboard. Collection of the deceased from the mortuary by the funeral directors is only permitted between the times:

8.30-12.00 and 13.00-16.00 Monday to Thursday
8.30-12.00 and 13.00-15.30 Friday

2.3 Laboratory Enquires

Histology Reports enquiries: office	ext 2563
Frozen section Requests:	ext 2566
Technical Advice Histology laboratory:	ext 2570
Mortuary Enquires	ext 2361
Clinical Advice and Interpretation	ext 2725

2.4 Laboratory Management

Several Key personnel are involved in the management of Cellular Pathology at Wirral University Teaching Hospital NHS Foundation Trust

Mrs Joanne Evans joanneevans1@nhs.net
Cervical Screening programme lead, Ext 2556

Mr Alistair Armstrong alistair.armstrong@nhs.net
Cellular Pathology Service Manager and Quality Manager, HTA Designated Individual (DI) Ext 7759

Mrs Helen Clarry helen.clarry@nhs.net
Histology Operations Manager Ext 2666

Mr Mike Murphy mike.murphy1@nhs.net
Mortuary Manager Ext 2361

Dr Anshu Awasthi anshu.awasthi@nhs.net,
Consultant Histopathologist, Departmental Laboratory Director and Consultant Service Lead (CSL)

PATHOLOGY DIRECTORATE AND DIAGNOSTICS AND CLINICAL SUPPORT DIVISION

Dr Simon Lea simon.lea@nhs.net
Divisional Clinical Service Lead

Alex Warrington alex.warrington@nhs.net
Pathology Manager

Divisional Manager
Paul McNulty paul.mcnulty@nhs.net

2.5 Consultant Pathologists and Specialty Doctors

Cellular Pathology currently employs highly qualified and experienced consultant pathologists who cover a broad range of specialities and are available for clinical advice and interpretation of reports if required. All the consultants can be contacted through their secretarial team on ext 2725 or by email.

Dr David A Agbamu david.agbamu@nhs.net
Consultant Histopathologist, Lead Colorectal Cancer Histopathologist, Lead Haematopathologist,

Dr Mohanad Alalusi m.alalusi@nhs.net
Consultant Histopathologist, Lead Medical Renal

Dr Anshu Awasthi anshu.awasthi@nhs.net,
Consultant Histopathologist, Lead Liver Histopathologist

Dr Ushra Azhar ushraazhar@nhs.net
Consultant Histopathologist, Lead Thyroid Histopathologist, Lead Upper GI Cancer Histopathologist, Lead Breast Histopathologist

Dr Krishna P Gumparthy krishna.gumparthy@nhs.net
Consultant Histopathologist, Lead Dermatopathologist, Lead Respiratory Cancer Histopathologist

Dr Keloth Pradeep Kpradeep@nhs.net
Consultant Histopathologist, Lead Gynaecological Histopathologist

Dr Vinutha Thonse Vinutha.thonse@nhs.net
Consultant Histopathologist and Lead Cervical Histology

Dr Chris Holmberg cholmberg@nhs.net
Consultant Histopathologist

Dr Manpreet Kaur manpreet.kaur76@nhs.net
Speciality Doctor

Patient Consent

The laboratory is not involved in taking specimens and assumes that appropriate consent has been taken by the clinician when the patient consents to the procedure.

There are circumstances when the laboratory would need to see consent documentation.

- The release of material to clinical trials and studies – The material will not be released until consent has been seen.
- Request for paediatric post-mortem examination – The laboratory and mortuary can not refer these cases to alder hey without appropriate consent information been sent with the foetal death.
- Removal of tissue from a deceased for organ donation purposes – appropriate organ donation consent documentation.

Request Form Completion and Requesting Tests

3. Request Form Completion and Requesting Tests

3.1 Requesting Histopathology (electronic and paper)

The department is committed to increasing the use of electronic ordering. Please only use paper copies if there is an issue with the IT System or a specific reason a paper request must be used. The department will accept paper requests from areas that have no access to electronic ordering.

GP Requesting of tests.

GP requesting is usually via ICE system but may be performed manually using the request forms below when ICE is not available.

- Manual Request form Produced by the GP Practice for Histopathology requesting when there is no access to ICE or in a period of downtime of the system.

Multiple specimens from the same patient may be submitted on the same request form provided they are clearly identified by site on the specimen container.

Hospital Requesting of Tests

Hospital requesting is usually via Cerner Millennium but may be performed manually using the request forms described below in times of IT system downtime or the unavailability of Cerner Millennium in the area the procedure has been carried out in.

- A5 card with yellow/orange header band (or locally printed GP request form) for Histopathology and non-gynaecological cytology used in times of IT system downtime or where there is no connection to IT systems.
- Green Unisoft request form for endoscopy biopsies

Multiple specimens from the same patient may be submitted on the same request form provided they are clearly identified by site on the specimen container.

Hospital Requesting of Foetal Post-Mortem Examination

- Request for Placental Examination form, obtainable from the department of Histopathology

- Royal Liverpool's Children's Hospital (RLCH) Placenta Request Form if referral to this hospital is required.

- Foetal samples 14-24 weeks gestation for examination at RLCH require a completed RLCH Consent Booklet and RLCH request form as well as 6 case sheet stickers and a copy of the cases notes for the episode.

- All Products of Conception or Surgical Termination of Pregnancies must have a completed Landican Cremation Form as well as the Histopathology request form.

3.2 Data Requirements for Request Forms

It is vital that COMPLETE demographic data is supplied:

- Full name with Forename and Surname
- Date of birth NOT age
- Hospital case sheet number or Patient NHS number
- Sex
- Specimen type (anatomic location)
- Date and time of collection of the specimen
- GP or Clinical Consultant's name
- Location of the source of specimen. (Ward, OPD, GP, etc)
- Name and bleep number of a contact doctor for biopsies or samples designated as urgent.

Please note that the laboratory cannot process samples unless supplied with two unique identifiers on the request form of which one **MUST** be the full name and the second either the patient's hospital case sheet number, patient's NHS number or patients full Date of Birth

Reports will be sent to the requesting clinician unless otherwise specified on the request form.

Clinical Data

A brief but RELEVANT summary of clinical details is essential, and Previous Histology or Cytology case number, if available. Please indicate the patients return clinic date if known.

Give as precise an anatomic location as possible; also, laterality, e.g. left, right, dorsal, ventral etc. SPECIAL INFORMATION REGARDING MARGINS SHOULD BE NOTED and marked accordingly (e.g., long suture = lateral; short suture = inferior)

Follow the established guidelines for the handling of hazardous materials e.g., AIDS, TUBERCULOSIS, HEPATITIS. Specimens in this category must be identified on the request form and if possible, a 'DANGER RISK OF INFECTION' label should be used.

Specimen Requirements and Handling

4. Specimen Requirements and Handling

4.1 Labelling of Specimens

For the laboratory to process the specimens it is imperative that they are labelled adequately to enable laboratory staff to easily identify which patient they arise from.

The laboratory cannot process samples unless supplied with two unique identifiers on the specimen pot of which one **MUST** be the full name and the second either the Patient's hospital case sheet number, patient's NHS number or patient's full Date of Birth. Without this minimum information the laboratory may reject the specimen and request. Please see section 4.2 for the laboratory's rejection policy. In instances where the patient's name is not appropriate/available a unique number may be used e.g., in Accident & Emergency, or Genital-Urinary Medicine clinics. All specimens should be legibly hand-written on the specimen container if a Cerner or WROCS label is not used.

If more than one specimen from the same patient attributed to a case is sent, they should be clearly indicated as part 1, 2, 3 etc with a note on the request form as to what each part is and where it has come from anatomically e.g. 1 Gastric, 2 Duodenal or 1 Skin from upper back, 2 Skin from leg. The specimen should also have a description of the specimen site.

4.2 Laboratory Policy for Rejecting Specimens

All specimens will be rejected if they are:

- Unlabelled
- Incorrectly labelled.
- If the minimum data (as detailed above in section 4.1) is missing from either the request form or the specimen.

Exceptions that may be initiated by the laboratory to allow processing include.

- **Second identifier missing from specimen only.**

E.g. "John Smith DOB 12.02.56" on the request form and "John Smith", only, on the specimen – provided that the specimen is physically attached to the request form.

- **Minor Discrepancies**

E.g., "John Smith DOB 12.02.56" on the request form and "John Smythe DOB 12.02.56" on the specimen container. The minor discrepancy is recorded on the form and the discrepancy is noted in the report.

- **Name abbreviations and diminutive forms of names**

For example, Jo Smith instead of Josephine Smith or Bill Smith instead of William Smith or Tony Smith instead of Anthony Smith.

- **Date of birth given has one and only one digit incorrect and there is a third identifier such as hospital number that is correct**

For example, when the name and hospital number are both correct on the tube and form but the written date of birth differs by one digit such as DOB 12.02.52 instead of 12.02.56.

Exceptions initiated by the Laboratory when it may consider the sample irreplaceable.

These exceptions may be initiated to allow processing when specimens are irreplaceable:

Criteria for irreplaceable specimens:

- Where there is significant added risk to the patient in obtaining a further sample
- Where the specimen is unique
- Where timing of the specimen is critical

These may include.

- Cerebral Spinal Fluid
- Operative specimens
- Complete excision biopsy
- Needle aspirations for Cytology
- Samples taken during Post-Mortem Examination

Action to be taken on receipt of an irreplaceable specimen, which is unlabelled or significantly mislabelled.

The laboratory will inform the ward/requesting clinician that for this sample to be processed the requesting clinician will need to identify the sample and re-label the specimen and take the responsibility for the specimen. It is then down to the

reporting consultant to whether they are satisfied enough to report the specimen. A Clinical Incident form will be completed by laboratory staff and sent to Risk Management.

4.3 Handling Hazardous Specimens.

Specimens arising from patients with a known or suspected transmissible disease (e.g., Hepatitis, HIV, Tuberculosis) **MUST be clearly labelled** as such to prevent unnecessary risk to laboratory staff.

4.4 Handling hazardous Chemicals

Handling Of 10% Buffered Formalin:

Formaldehyde is classified as a hazardous chemical and is a skin, eye, and respiratory irritant. Ensure when handling the chemical that protective gloves are always worn and when handling large quantities, where splashes of the chemical are likely to occur, that eye protection is used. When pouring large quantities of formaldehyde ensure that the room is well ventilated, and this activity is not carried out in a confined space.

When storing formaldehyde ensure that containers are tightly closed and are stored in a dry, cool well-ventilated place. Keep formaldehyde only in properly labelled containers to avoid risk of accidental exposure.

In the event of a spillage, ensure adequate ventilation and absorb the spillage using formaldehyde control granules. Sweep up and dispose of in a suitable container and flush traces away using water. If the spillage is very large then the hazmat team from the fire brigade may be required to deal with the spillage. Small spillages (100ml) can be absorbed using absorbent roll and then this material bagged up and sealed to eliminate the release of further fumes. Small spillages do not need to be dealt with using formaldehyde control granules as the fumes produced would be within the acceptable exposure limits.

For further advice regarding the handling, storage and dealing with spillages please contact the Histopathology department for advice.

4.5 Specimen Containers

Due to the wide range of Histopathology and Non-Cervical Cytological specimens several key container types exist as follows:

- White or yellow topped pre-filled 60ml Containers of formalin

Suitable for small specimens for histological testing including biopsies, and smaller resection specimens e.g., skin punches, currettings, excisions

- 350ml White topped Specimen jars without fixative

Suitable for larger histological specimens e.g., gallbladders, large skin resections, femoral heads, and ovaries. These pots are filled with an appropriate amount of formalin by the collecting clinician.

- Specimen Buckets

Specimen Buckets for large histopathological resections e.g., breast, colon, kidney. These pots are filled with an appropriate amount of formalin by the collecting clinician unless delivered to the laboratory fresh. Theatres can order these from the Histopathology department.

- 50ml Sterlin Pots or 25ml Sterile universal Container

Suitable for samples sent for non-gynaecological testing e.g., urine, pleural fluid, and ascitic fluid.

- Prefilled CytoLyt Containers containing 25ml Cytolyt preservative (commercially bought). Used for the collection of bronchial Brush Specimens.

- Prefilled CytoRich Red Containers containing 10ml of CytoRich preservative (commercially bought). Used for the collection of EBUS and EUA samples for analysis.

Please note the amount of formalin should be 10 x the specimen size to ensure adequate fixation.

Transportation of Specimens

5. Transportation of Specimens

5.1 Transportation from GP Practices

Please Note all specimens sent to the Histopathology laboratory must be placed in the **WHITE** Histopathology transport bags inside Sealed Transport bags

Histology and Non-Gynaecological Specimens

All specimens taken within General Practice are transported to the laboratory via the MCS transport courier via the main laboratory medicine specimen reception. There is no time limit for specimens requiring histological testing to get to the laboratory although any delay will cause a delay in the time taken to report the specimen. Non-Gynaecological specimens should be dispatched to the laboratory immediately or as soon as possible after collection as they can deteriorate rapidly over a short period of time.

5.2 Transportation from Arrowe Park Hospital and Clatterbridge Hospital

Please Note all specimens sent to the laboratories must be placed in the **WHITE** Histopathology transport bags inside the transport boxes

If the specimens are taken within Arrowe Park Hospital they can be transported to the laboratory via the porter system through the main laboratory medicine specimen reception. If the specimens are taken within Clatterbridge Hospital these are transported via the portering system to central point at ward 2, where they travel via the inter-hospital transport system to the main laboratory medicine specimen reception where they are transported to the laboratory via porters. A large delay for resection specimens and whole organs may lead to irreversible damage to the specimen as the specimens need to be opened by the pathologist to allow the fixative into the centre of the specimen.

Renal biopsies and skin biopsies for immunofluorescence should be despatched immediately to the Histopathology laboratory, by taxi from Clatterbridge Hospital, Countess of Chester or by porter from Arrowe park hospital. It is essential to direct the carrier to Histopathology. As these specimens are collected in saline, if they are not received in the laboratory within 2 hours of been taken this will lead to irreversible damage to the samples.

Frozen Sections and Fresh specimens must be delivered directly to the Histopathology department after been collected by either a porter or a theatre staff member, any delay will lead to irreversible damage to the samples.

Any samples sent through the post must comply with EU regulations regarding packaging and sending of biological specimens through the post.

Urgent Reporting

6. Urgent Reporting

Occasionally it may be necessary for the requesting clinician to highlight a specimen as clinically urgent. If an urgent report is required, please ensure that it is clearly identified on the request form. Urgent requests should be sent to the department of Histopathology without delay. Once received, urgent cases will be highlighted by the laboratory staff and prioritised appropriately in the departmental workload.

If a request becomes urgent after the department has received the request, please contact the medical secretaries who will locate the case and change its status to priority.

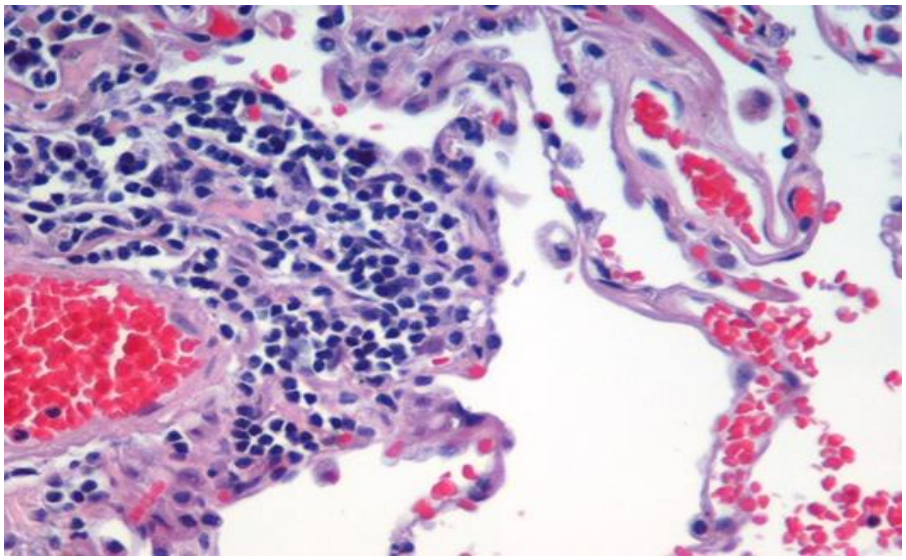
Histopathological Testing and Requirements

7. Histopathological Testing and Requirements

7.1 General Requirements

Histopathology is the study of microscopic changes in diseased tissues. Samples are either received fresh (unfixed) or in the histological fixative Buffered Formalin and are processed to paraffin wax to preserve and stabilise the tissue. Wax impregnated tissue is then cut on a microtome to produce ultra thin sections of tissue, which are mounted onto glass slides and stained prior to light microscopy. This analysed by a consultant histopathologist to make a diagnosis.

A section of lung with Haematoxylin and Eosin for Routine Histological Diagnosis



Clinical Advice and interpretation is available at all times during the laboratory's opening hours from the relevant consultant Histopathologists by the contact information on pages 8 and 9. Request for advice and interpretation can be made through e-mail or by phone.

7.2 Specimen Collection

Ensure that the specimen is large enough to be representative. This may save you a repeat procedure! The tissue biopsy or entire specimen should be placed in a clean container of 10% neutral buffered Formalin (see section 7.4 for specimens that require different collection and fixation). **The volume of fixative should be**

approximately ten times the volume of the specimen. See section on handling of 10% buffered formalin for risk and hazards associated with this chemical. If microbiological investigations are required do not place the tissue in fixative. Never send specimens in normal saline.

Specimens may be collected at any time (see section 7.4 for specimens that require the laboratory being informed about the collection of certain specimens). If urgent small (endoscopic or needle core) specimens are received before 4.30pm they will normally be able to begin to be processed the same day as long as they have been in fixative for longer than three hours. Larger specimens will usually be fixed overnight and begin processing the following day. Cancer resections and other large resections may require 2-3 days of fixation before being suitable for cut-up by a Histopathologist.

7.3 Turnaround Time (TAT)

90% of all histological cases are reported within three weeks of the receipt of the specimen, 80% are reported within two weeks of the receipt of the specimen by the laboratory.

The department has specific local agreements in place for cancer turnaround times with different specialities and aims to ensure all cases required for MDT are reported in time for the MDT where this is technically possible and that cancer pathway targets are met.

The department is currently working towards the Royal College recommendations for the reporting of histopathology cases where provisional expectations are that 80% of cases would be reported within seven calendar days and 90% of all cases are reported within ten calendar days. Current Turnaround times of tests are available on request in writing from the Cellular Pathology Manager.

7.4 Special Considerations Affecting the Performance of the Test and the Interpretation of the Results

1. Multiple Specimens

Keep specimens from different anatomical locations in separate containers, and separately labelled. A single request form may be used.

2. Endometrial samples

a) Supply date of LMP and cycle.
b) Do not leave specimen in vabra cassette, place it in a plastic screw-topped container of 10% neutral buffered Formalin.

c) Supply information about hormone therapies e.g. oral contraceptives, progestogen therapy, hormone replacement therapy, tamoxifen therapy, Zoladex, etc.

3. Cervical biopsies

Supply any relevant previous cytology details if known.

4. Renal biopsies

These specimens **MUST** be collected in Saline and **NOT** in 10% Formalin, collection in formalin will mean essential tests such as immunofluorescent studies cannot be carried out and the diagnosis may be compromised.
Renal biopsies must be despatched immediately to the Histopathology laboratory, by taxi from Clatterbridge Hospital, Countess of Chester or by porter from Arrowe Park Hospital. It is essential to direct the carrier straight to Histopathology. As these specimens are collected in saline, if they are not received in the laboratory within 2 hours of been taken this will lead to irreversible damage to the samples. The laboratory **MUST** be informed when a renal biopsy is been performed to ensure it is ready for its arrival, and to investigate if the biopsy has not been delivered to the laboratory

5. Skin

Inflammatory dermatoses should preferably have a clinical differential diagnosis.

Prior notification is required when direct immunofluorescence is contemplated. The specimens should be sent fresh. Please **DO NOT PLACE THE SPECIMEN IN FIXATIVE** and the specimens must be despatched immediately to the Histopathology laboratory, by taxi from Clatterbridge Hospital or by porter from Arrowe Park Hospital. It is essential to direct the carrier straight to Histopathology. As these specimens are fresh and unfixed, if they are not received in the laboratory within 2 hours of being taken this will lead to irreversible damage to the samples

6. Placentas

Placentas should only be sent to Histopathology when there is a clear clinical indication for doing so. All requests for Histopathological examination must be accompanied by information pertinent to the interpretation of the pathologic findings. Information transmitted should include previous obstetric history, obstetric estimate of gestational age, route of delivery, birth weight, sex, Apgar scores at 1 and 5 minutes, maternal and fetal complications of pregnancy, labour, and delivery. All foetal death cases requiring post-mortem examination are referred to Liverpool Alder Hey Children's Hospital. On delivery to the laboratory the specimen must be accompanied by the post-mortem request form and the appropriate section of the mother's medical notes.

7.5 Intraoperative Frozen Sections

Frozen sections for rapid diagnosis should be requested by a medical practitioner (by telephoning ext 2566) giving the laboratory as much notice as possible, (for an elective frozen section at least 24 hours is required). Requests should be made sparingly, never for convenience, as valuable tissue may become irretrievable for routine paraffin sections. Frozen section reports are provisional and will be confirmed by paraffin section.

Specimen Collection and transport:

1. Do not place the specimen in fixative, they **MUST** be sent fresh (un-fixed).
2. On the request form write the telephone extension number to which you would like the report to be phoned.
3. Explain the urgency of the situation to the porter and ensure they take the specimen directly to Histopathology.
4. At Clatterbridge an urgent taxi must be dispatched with the specimen as soon as it is collected and must be delivered directly to the Histopathology laboratory.

The process from specimen receipt in the laboratory to verbal report issued takes no longer than **45 minutes,** however this time may be shortened or lengthened slightly depending on the nature of the sample received and the complexity of the diagnosis.

Some tissues are **not suitable** for frozen section unless absolutely clinically required. Examples include tuberculous lesions, specimens from patients with viral hepatitis and patients who are HIV positive. These specimens pose a high risk to the laboratory staff conducting the frozen sections. Please contact the laboratory manager or consultant histopathologists is there is any doubt on whether the specimen is suitable for frozen sectioning.

7.6 Time Limits for Requesting Additional Tests

There is no time limit for requesting additional tests on histological specimens, as the specimen is stored in a paraffin-embedded tissue block which keeps the tissue in a state valid for all additional tests (Breast receptor testing, gene analysis ect).

All residual non-processed tissue is disposed of four weeks after the release of the report to the requestor.

Non-Gynaecological Cytology Testing and Requirements

8. Non-Gynaecological Cytology Testing and Requirements

8.1 General Requirements

The department offers a full range of non-gynaecological diagnostic cytology testing including fine-needle aspiration, respiratory sample testing, urine testing, cerebrospinal fluid (CSF) testing and serous effusion examination for the detection of cancerous cells.

Clinical Advice and interpretation is available at all times during the laboratory's opening hours from the relevant consultant histopathologists via the contact information on pages 8 and 9. Requests for advice and interpretation can be made through e-mail or by phone.

8.2 Specimen Collection

Multiple specimens: keep specimens from different anatomical locations in separate containers, and separately labelled. A single request form may be used. Supply details of any relevant previous cytology or histology.

As for Histopathology; follow the established procedures and identify specimens with the appropriate hazard-warning label. Hospital requests for non-gynaecological cytology are usually made via the Cerner Millennium hospital system. GP requests are usually made via WROCS (Wirral Remote Ordering Communications System).

<u>Sputum Samples</u>

Sputum cytology is a deprecated investigation for pulmonary malignancy with a high false negative rate and should be avoided whenever possible. Specimens from the hospital should only be submitted after discussion at the Lung Cancer MDT meeting. The physician arranges the specimen collection. The specimen should be an early morning specimen and care should be taken to ensure that the specimen is indeed sputum and not just saliva, the assistance of the physiotherapy department may be required to obtain a deep cough specimen. Maximum sensitivity is achieved by sending three consecutive early morning specimens, each one despatched immediately to the laboratory; stale specimens are not suitable for analysis. The specimen should be expectorated into a sputum pot and sent to the cytology department directly. The laboratory processes the sample using ThinPrep technology and prepares fixed liquid based preparations. It is essential sputum

samples are received as soon as possible to stop the degradation of the sample due to the nature of the specimen.

Bronchial Brushings

Large numbers of cells are obtained from an area(s) of the bronchial tree, which have a suspicious appearance to the clinician. The primary use for the technique is in the diagnosis of malignancy. A respiratory physician undertakes bronchial brushings during Endoscopy. The Endoscopic brush should be cut with metal cutters and the brush end placed in a ThinPrep CytoLyt vial. The CytoLyt vial should be labelled with the patient's name, date of birth, hospital number, ward and collection date either manually or using a case note adhesive label. The specimen should be delivered promptly to the laboratory to facilitate processing and reporting in time for inclusion in relevant multi-disciplinary meeting. In exceptional circumstances when prompt transit is not feasible, the specimen may be safely stored at room temperature. The specimen **must not** be stored in the fridge as a temperature range of 15-30°C is required for the CytoRich red solution.

Bronchial Washings

Some lung cancer patients may not exfoliate malignant cells into sputum samples. In addition, certain (e.g. peripheral) tumours may not be visible at bronchoscopy. Bronchial washing samples can harvest cells that may have been hitherto unavailable, furthermore selective bronchial brushings may help localise a tumour in cases of positive sputum cytology but negative x-rays. In other non-neoplastic conditions, it is possible to express certain patterns of cellularity. A respiratory physician in the Endoscopy Suite performs bronchial washings. Bronchial washings are collected into physiologically normal saline and should be sent directly to the cytology laboratory to facilitate processing using ThinPrep liquid-based technology and for reporting in time for inclusion in relevant multi-disciplinary meetings. In exceptional circumstances when prompt transit is not feasible the specimen may be left in a cool place away from sunlight but MUST NOT be placed in a refrigerator, as the storage interval for the regent in the specimen is 15-30 degrees centigrade.

FNA (Fine Needle Aspiration) Cytology

Fine Needle Aspiration may be used to confirm a diagnosis of malignancy or for primary diagnosis in selected patients. Generally, only discrete lumps are suitable for the procedure; diffuse or deeply seated lumps are less suitable and are more likely to yield an unsatisfactory specimen. A radiologist performs aspirations under ultrasound. Please note the consultant pathologists DO NOT perform FNAs and all requests for an FNA procedure need to go through the Head and Neck clinic or a radiologist.
A small amount of tissue is aspirated and spread directly onto glass slides labelled, in pencil, with the patient's name and hospital case sheet number/Date of Birth. The

slides should be placed into a plastic slide box and sent to the histology department. If only a tiny amount of specimen is obtained, then the syringe and needle contents may be flushed into 5-10ml cytology collection fluid available from the Histology Department. It is essential that all FNAs collected are hand delivered to the department as delays to the processing of the sample will detriment the preservation of the cells that are spread on the slides and may affect interpretation.

Body cavity Fluids

The cytological examination of body cavity fluids is used mainly for the detection of malignant cells. Occasionally other information may be ascertained e.g.. type and degree of inflammation, parasites identified, foreign material or crystals, cholesterol and protein concentrations. Cells rapidly deteriorate in these fluids; specimens should be sent as quickly as possible for analysis, specimens may be stored for a matter of hours in a refrigerator. The patient's medical team collects the specimen. The specimen is then sent to the histology department. If a clot develops in the specimen the laboratory will process the same for histology. If a large sample is required for additional immunological investigations of a suspected malignancy please contact the laboratory on ext 2556 to arrange for a larger specimen container (500ml).

Cerebrospinal Fluid

The cytological examination of CSF is primarily for the detection of malignant cells. Occasionally infections can be identified e.g. cryptococcus. The specimen is collected into a sterile universal container. The specimen must be dispatched immediately to the histopathology lab (not the main pathology lab).

Synovial Fluid

Please note this test is not performed by the Histopathology Department. All requests for this type of testing must be made through the **Microbiology Department**

Urine Samples

Normal urine contains very few cells. The cells present are transitional cells from the bladder and to a much lesser extent the ureters and renal pelvis. In addition squamous cells may be present from an area of squamous metaplasia or as contaminants from the vagina or penis. Other cells present may include leucocytes and histiocytes. A mid-morning "clean catch" specimen amounting to 20ml is required. A common misunderstanding is that early morning specimens (EMU) make the best specimens; the reverse is the case - they contain the most degenerate cells. (EMU specimens are for the investigation of TB - see Microbiology user manual). The specimen should be despatched immediately to the laboratory. Any cells present undergo degenerative changes very quickly due to the hypertonicity of the

urine and also due to any bacteria present. Avoid collecting urine that cannot be delivered to the laboratory before 1700 hours. Urines that have stood overnight are almost useless unless refrigerated. Please ensure that an appropriate amount of urine is collected to ensure the specimen is adequate. An ideal volume is between 20 and 50ml, less than 20ml of urine is a sub-optimal specimen. In some cases urines can be requested by the GP practice and the Hospital clinic for the patient to produce at home. In these circumstances it is essential the patient ensures the specimen is labelled correctly with their full name, and date of birth and the collection date and time and the specimen must be taken to the GP practice/hospital out-patient department on the day it is produced.

<u>EBUS and EUA Samples</u>
Endobronchial ultrasound trans-bronchial needle aspiration (EBUS-TBNA) enables visualisation and sampling of Mediastinal, Central or Hilar lesions and Lymph Nodes within the Tracheo-Bronchial Tree. Cells of the tumour or Lymph Nodes are taken during the procedure. This procedure can be used for patients who are being tested for various diseases, including lung cancer. The aim of the procedure is to help reach a diagnosis and, in patients with lung cancer, to establish whether the disease has spread beyond the lung.

In a similar manner, an endoscopic ultrasound aspiration (EUA) allows clinicians to visualise the Gastrointestinal Tract Wall, the Liver, Pancreas, Lymph Nodes, and Bile Ducts. Fine needle cores can be taken during this procedure allowing for the diagnosis of cancer as well as aiding in the staging of the tumour.

The Endobronchial ultrasound trans-bronchial needle aspiration (EBUS-TBNA) or endoscopic ultrasound aspiration (EUA) should be placed in commercially bought specialist 20ml pots containing CytoRich red solution. The CytoRich red specimen pot should be labelled with the patient's name, date of birth, hospital number, ward and collection date either manually or using a case note adhesive label. The specimen should be delivered urgently to the laboratory to facilitate processing and reporting in time for inclusion in the relevant multi-disciplinary meetings. In exceptional circumstances when prompt transit is not feasible, the specimen may be safely stored at room temperature until delivery the next day. The specimen **must not** be stored in the fridge as a temperature range of 15-30°C is required for the CytoRich red solution.

8.3 Turnaround Time (TAT)

90% of all non-gynaecological cases are reported within three weeks of the receipt of the specimen, 80% are reported within two weeks of the receipt of the specimen by the laboratory.

The department has specific local agreements in place for cancer turnaround times with different specialities and aims to ensure all cases required for MDT are reported in time for the MDT where this is technically possible.

The department is currently working towards the Royal College recommendations for the reporting of pathological where Provisional expectations are that 80% of cases would be reported within seven calendar days and 90% of all cases are reported within ten calendar days. Current Turnaround times of tests are available on request in writing from the Cellular Pathology manager.

8.4 Special Considerations Affecting the Performance of the Test and the Interpretation of the Results

The special considerations involving non-gynaecological requests that affect the performance of the test and interpretation of the results is the time between the specimen collection and the arrival in the laboratory, as with time the specimens degenerate making interpretation difficult and reducing the performance of the test

To avoid degradation to the cells and overgrowth of bacteria urine specimens should arrive within 24 hours of being taken, and if having been stored before delivery should be stored in a fridge. CSF specimens should arrive immediately as they are an irreplaceable specimen.

FNA specimens need to arrive immediately as the length of time passed affects the fixation and the type of test allowed to be performed. Respiratory and serous fluids need to arrive as soon as possible, and at latest within 24 hours of the specimen collection, especially with respiratory specimens, to facilitate processing using ThinPrep liquid-based technology and reporting in time for inclusion in relevant multi-disciplinary meetings.

In terms of sample volumes ensure that an appropriate amount of urine is collected to ensure the specimen is adequate. An ideal volume is between 20 and 50ml, less than 20ml of urine is a sub-optimal specimen.

In terms of refrigeration before sending to the laboratory, it is important that Bronchial specimens collected in CytoLyt, EBUS and fine needle aspiration specimens collected into CytoRich red **are not** stored in a refrigerator. The CytoRich red and Cytolyt reagents have a temperature storage range of 15-30°C.

8.5 Time Limits for Requesting Additional Tests

Specimens are stored in both saline or preservation fluid for four weeks after the report has been verified and released and are available for addition tests within this time period, although the optimum for the request of additional test is within two

weeks. Requests for addition tests for specimens older than four weeks after the results have been released are not acceptable as the specimen will have been discarded.

Mortuary Services

9. Mortuary Services

9.1 Confirmation of Death

Please refer to the trust Death and Administration Policy and Procedure

9.2 Deaths to be reported to the Coroner

Please see Appendix 2 of the trust Death and Administration Policy and Procedure

9.3 Requesting an Autopsy

The post-mortem examination (autopsy or necropsy) plays a very important role in clinical audit, research and education. Major unsuspected diagnoses are found in up to 39% of hospital or clinical post-mortem examinations, and additional information may be obtained in 80% of cases.

A post-mortem examination may be held in one of two circumstances:
1. Coroner's post-mortem examination (non-suspicious cases).
2. Coroner's post-mortem examination (suspicious cases) (Forensic or Home Office post-mortem examination).

Please note the department does not provide a consented adult hospital post-mortem service.

Coroner's Post Mortem Examination (Non-Suspicious Cases)

Her Majesty's Coroner has absolute power to direct that a post-mortem examination be carried out. No permission is necessary from the next of kin. If you suspect that death may be related to an unnatural event, then the case must be referred to the coroner or his officer through the medical examiner.

Coroner's Forensic Post Mortem Examination (Suspicious Cases)

A forensic post-mortem examination is conducted when there is any suspicion that death may be due to murder. It is the coroner's responsibility to contact the mortuary technician and the Home Office Pathologist. Out-of-hours cover is provided by the mortuary staff to cater for all types of mortuary enquiries. Those in attendance at a forensic post-mortem examination in addition to the mortuary technician and pathologist are the coroner's officer, photographers and Scenes of Crime officers.

The Wirral University Teaching Hospital mortuary does not conduct Forensic Post-Mortem Examinations.

9.4 Deaths of Patients with Serious Infections

The following provides guidance to the wards relating to the appropriate use of body bags when transferring infectious/leaking bodies from the wards to the mortuary.

Use of Body Bags
Following last offices, bodies that are to be transferred from the ward to the mortuary should be placed in a body bag in the following instances:

- When the body is known to be leaking
- When there is a risk of leaking (e.g. congestive cardiac failure with peripheral oedema, intestinal obstruction, etc, when IV lines, drains, etc, must be left in situ, or in cases where a Coroner's inquest is indicated)
- When the body is extensively traumatised
- When the deceased is recognised as infectious, according to the list below

Body Bag Availability

Body bags are stored in the following locations:

Equipment Library Arrowe Park
Conway Ward Clatterbridge Centre for Oncology

Category	Infection	Body Bag
Low risk	Acute Encephalitis	No
	Chicken-pox	No
	Cryptosporidiosis	No
	Clostridium Difficile	No
	Dermatophytes	No
	Legionellosis	No
	Leprosy	No
	Lyme Disease	No
	Measles	No
	Ophthalmia Neonatorum	No
	Orf	No
	Psittacosis	No
	Rubella	No
	Staphyloccocus Aureus (MRSA)	No
	Whooping Cough	No

Medium Risk	Acute Poliomyelitis	No
	Cholera	Yes
	Diptheria	Yes
	Dysentry	Yes
	E. coli 0157 and other shiga toxin producing bacteria	Yes
	Food Poisoning	No
	Haemorrhagic fever with renal syndrome	No
	HIV / AIDS	Yes
	Leptospirosis (Weil's Disease) – depending on condition of the body	No
	Malaria	No
	Meningococcal infection	Yes
	Paratyphoid fever	Yes
	Q fever	No
	Relapsing fever	Yes
	Tuberculosis	Yes
	Typhoid fever	Yes
	Typhus	Yes
	Viral hepatitis (A)	No
High Risk	Transmissible Spongiform Encephalopathies	Yes
	Invasive Streptococcal Disease (Group A)	Yes
	Viral Hepatitis (B, C, non-A, non-B)	Yes
Rare (High Risk)	Anthrax	Yes
	Plague	Yes
	Rabies	Yes
	Smallpox	Yes
	Viral Haemorrhagic Fevers	Yes

Should the deceased require a body bag in accordance with the above list, a Danger of Infections sticker must be placed on the bag.
When the porters are removing the box from the ward, the Porters' Register Book must be completed, indicating reasons for use of a body bag.

When an infectious body arrives at the mortuary, one of the following Mortuary Technicians will contact the ward to establish the nature of the infection. The ward staff must identify the nature of the infection for the technician.

All bodies received by the mortuary from community deaths are placed into body bags.

9.5 Death Certification and Cremation Forms

Please see Appendix 2 of the trust Death and Administration Policy and Procedure

9.6 Release of Bodies to Funeral Directors

Hospital deaths

Funeral Directors/Drivers are required to produce the Hospital release form obtained from Bereavement Services. The Mortuary staff will not release the deceased without the appropriate documentation and completed release form. This includes any deaths that occur in the Accident & Emergency department that the coroner has asked the hospital doctor to complete a death certificate.

Coroner's deaths

For ALL Coroners-related deaths (regardless of whether it is signed by the GP or coroner's post mortem) for burial or cremation, funeral directors/drivers are required to bring to the mortuary the full name of the deceased, date of birth (or age) and their last known address. **Please note that mortuary staff will not release the deceased without the correct documentation and authorization from the coroner.**

Release of Body Out-of-Hours (Exceptional Circumstances)

Deaths that are under the Jurisdiction of the Coroner cannot be moved or transported out of the Coroner's Jurisdiction or released without the coroner's permission or authority. For bodies that need to be released out-of-hours due to religious reasons please contact the hospital switchboard who will put you in touch with the on-call mortuary technician to facilitate this process.

Governance and Assurance

10. Governance and Assurance

10.1 The Laboratory Quality Policy

Scope of Service:

To provide, through a timely and accessible process, a high quality, clinically lead, diagnostic service in Cellular Pathology that meets the needs of our users (who are patients, doctors, nurses, midwives, and other healthcare professionals) across the Wirral University Teaching Hospital Trust Sites (Arrowe Park Hospital & Clatterbridge Hospital) and Wirral PCT and West Cheshire PCT.

The Directorate of Laboratory Medicine commits to:

- Ensuring the service is committed to the highest standards of impartiality.
- Implementing and maintaining a Quality Management system and developing Quality objectives and policies for the delivery of services with focus on improving patient outcomes.
- Adhere to the policies and guidance adopted by WUTH and provided by NICE, ISO and other relevant National Regulatory Organisations
- Ensuring that the laboratory complies with all relevant Health and Safety legislation, Environmental legislation, regulations, and guidance to create a safe working environment for staff and visitors
- Ensuring that the Quality Objectives and the Quality Management system and all procedures relevant to their work are communicated to and understood by all staff of all levels within the laboratory.
- Ensuring that all staff has the necessary training and resources to correctly undertake their tasks in the delivery of the Quality objectives and policies of the Department
- Ensuring that all staff will keep their skills and knowledge up to date through participation in relevant registered Continuing Professional Development schemes and through the Joint Annual Review processes of WUTH.
- Demonstrate a commitment to and achievement of good professional practice
- Conducting regular reviews and audits of all Quality Systems to ensure that objectives are met

The Laboratory will comply with the ISO standard 15189 and is committed to:

- Staff recruitment, training, development, and retention at all levels to provide a full and effective service to its users.
- The proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service.
- The collection, transport, and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations.
- The use of examination procedures that are fit for intended use and will ensure the highest achievable quality of all tests performed.
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful as well as providing timely access to clinical and professional advice.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, to produce continual quality improvement plans.

This policy is reviewed annually as part of Management Reviews.

10.2 Internal Quality Assurance

Regular internal quality checks and audit procedures are carried out to ensure the quality and safety of the results provided, as follows: (not an exhaustive list)

- Integrity of patient /sample details
- Quality control checks throughout examination procedures
- Audit of quality: equipment, procedures, staff competency and reporting procedures
- User satisfaction surveys
- Key performance indicators based around key areas of the department including, performance, staffing, risk assessment, documentation and finance

10.3 External Quality Assurance

The laboratory participates in several external quality assurance schemes to ensure the quality of the service. Participation in the following technical schemes is currently undertaken:

UK NEQAS for Cellular Pathology

- General Histopathology including frozen sections and mega blocks
- Scheme for Renal Biopsy
- Non-Gynaecological Diagnostic Cytology

- Direct Immunofluorescence

UK NEQAS for Immunocytochemistry

- General Scheme
- Breast Scheme (Hormone Receptors and her-2)
- Lymphoma
- Alimentary Tract - Lynch Syndrome

Histopathologist Interpretative schemes

- North West Region Histopathology General Scheme
- National GI EQA Scheme
- National Dermatopathology EQA Scheme
- National Liver EQA Scheme
- National Renal EQA Scheme
- National Breast EQA Scheme
- National Urology EQA Scheme
- Non-Gynaecological EQA Scheme

10.4 Complaints Procedure

Wirral University Teaching Hospital is committed to patient centered care and to continuous service improvement. As part of this process the Trust will deliver an efficient and effective complaints procedure, not only because it is legally required to do so, but because it is committed to identifying and implementing service improvements and enhancing the patient experience as a result.

Complaints can be made by contacting the laboratory manager by email at alistair.armstrong@nhs.net, by phone on 051-604 7778 or in writing to the laboratory's address listed in the Key Information section addressing the complaint to Alistair Armstrong, Laboratory Medicine.

Concerns and complaints can also be raised directly with the Patient Experience Team by telephone, email or letter. There will also be an interview facility to enable service users to raise concerns and complaints with the Patient Relations Team through a face-to-face meeting.

Following a review of the correspondence received (including any discussion with the person who has contacted WUTH), all concerns and complaints received by the Patient Experience Team will be assessed and graded into one of the following categories:

Level 1 concern- This will be investigated as an informal concern that has the potential to be resolved quickly by front line staff within three working days. Level 1 concerns may be resolved verbally and do not require a written response unless

requested by the enquirer or decided on by the division as a more appropriate response. Any such written response may be signed off at departmental / divisional level, unless it has been received via a MP's office, in which case it is approved centrally by the Head of Complaints and signed by the Chief Executive Officer.

Where the concern has been raised via the Complaints and PALS Team, within one working day they will acknowledge receipt, register the concern on Ulysses Safeguard, and forward the concern to the appropriate department manager within the area concerned. That manager will contact the enquirer directly with a view to resolving the concern at a local level within three working days, or within an additional timeframe as agreed with the complainant. The department manager will then contact the Complaints and PALS Team to confirm that the matter has been resolved to the enquirer's satisfaction so Ulysses Safeguard may be updated, and the concern closed.

If no such confirmation has been received from the department manager within three working days, then the Complaints and PALS Team will escalate as appropriate to the divisional triumvirate, which will be held accountable for any lack of response. Routes of escalation include the automated daily reports and/or weekly progress review meetings by the Complaints and PALS Team with divisional senior management.

Where a concern takes is taking longer to resolve than 10 working days, consideration will be given to converting the matter to a formal complaint (maintaining the current clock-start date), according to the wishes of the person raising the concern.

Level 2 complaint- This is a formal complaint that should be acknowledged within three working days of receipt and responded to within 40 working days via a written response signed off at executive level. In the absence of the CEO, the deputy may act as delegated representatives to sign off level 2 complaint responses.

10.5 Policy for Protection of Personal Information

The Wirral University Teaching Hospital policy on the handling and protection of personal information has been produced to promote consistency with the way the Trust handles confidential and/or personal identifiable (staff/patient) information and to conform to the principles of the Data Protection Act 2018 and follows the 7 Caldicott principles.

All members of staff handling confidential and or personal identifiable (staff/patient) information whether it is paper based or electronic adhere to this policy to ensure patient care is not compromised and to comply with the legal requirements placed upon the Trust.

The trust commitments to personal Information:

- Information will be defined and where appropriate kept confidential under the provisions of relevant legislation.
- The Trust regards all personal identifiable information relating to patients as confidential.
- The Trust will establish and maintain policies to ensure compliance with the Data Protection Act 2018, Human Rights Act 1998 and the common law duty of confidentiality.
- The Trust regards all personal identifiable information relating to staff as confidential except where national policy on accountability and openness requires otherwise.
- The Trust respects the rights of patients and staff and will gain consent of individuals where necessary prior to disclosure of information.
- The Trust will establish and maintain incident reporting procedures and will monitor and investigate all reported instances of actual or potential breaches of confidentiality.
- The Trust will promote effective confidentiality practice to its staff through policies, procedures and training. All staff undertakes yearly mandatory Information Governance training.

Investigations Carried Out Through Third Parties

11. Investigations Carried Out Through Third Parties

Paediatric Pathology
Department of Paediatric Pathology
Royal Liverpool Children's Hospital NHS Trust

Renal Biopsy Electron Microscopy
EM Unit
Manchester Royal Infirmary

FISH, HODS, EGFR, p16, PDL-1 and other molecular tests
Royal Liverpool and Broadgreen University Hospital

Muscle Biopsies and Brain Investigations
Walton Centre for Neurology and Neurosurgery
University Hospital Aintree

Dermatology specialist opinion and testing
Guy's and St Thomas Hospital

Genomic requests
Manchester Genomics Laboratory

Oncotype DX genetic testing in breast
Genomic Health

Heart Investigations
St Georges Hospital
London

Histopathology Reporting
Backlogs Limited

IHC markers not in repertoire
HSL Diagnostics